Fundamental Aspects of Medicines

Note

Health and social care practice and knowledge are constantly changing and developing as new research and treatments, changes in procedures, drugs and equipment become available.

The authors, editor and publishers have, as far as is possible, taken care to confirm that the information complies with the latest standards of practice and legislation.

Fundamental Aspects of Medicines

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Preface

The taking of a medicine is one of the commonest interventions in healthcare. Every year, millions of prescriptions are dispensed by pharmacies, and there is increasing concern about the way in which medicines are used and how to provide support for carers. It is known that substantial quantities of medicines are not taken as recommended by prescribers and a wide variety of over-the-counter products are purchased and consumed. These alarming trends in the use of medicines arise at a time when the number of people aged over 65 within the population continues to grow – a situation that is hugely significant when considering how best to ensure the safety of medicines within a care setting.

This book provides an accessible practical reference and training resource on the use of medicines in the delivery of care. It will be of interest to care workers in residential or nursing homes and also to those who are supporting friends and family within the community.

Clearly, the use of medicines is an enormous subject to tackle within a small book, so we have not aimed to cover all areas in detail. A broad brush approach has been taken that aims to:

- use non-technical language where possible
- offer practical advice within a care context
- summarise information
- signpost readers to further reading and resources
- provide training exercises to consolidate the subject area.

How to use this book

Each chapter begins with a short scenario that aims to put the content of the chapter in a care context and demonstrate how the specific area of focus can be applied to everyday situations. There is a 'Checkpoint' where the reader is invited to answer some questions and encourage personal reflection before proceeding with the chapter. At the end of each chapter there are multiple choice questions to provide the opportunity for self-assessment.

An integral part of this book is the inclusion of case studies to consolidate practical issues and apply the knowledge explored in each chapter. There are

also some suggested practical activities that aim to contextualise the information. When referring to examples of medicines, comments have been included to enable the reader to appreciate some key effects, side-effects and possible interactions. However, it is important to appreciate that these effects are by no means comprehensive – the book is not intended as an exhaustive reference source. For detailed information about a particular medicine, the reader is advised to consult the data sheet that accompanies the product or to consult an authoritative reference source, such as the latest *British National Formulary*.

Our background within the pharmacy profession has brought us into contact with many different people working within a care setting. It has become increasingly clear that a resource on medicines is urgently required that is more accessible to the care worker and of wider benefit to the community. This book is our attempt to make some contribution towards this important requirement.

Jon Waterfield
Peter Rivers
May 2012

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Jon Waterfield registered as a pharmacist in 1984, having completed his degree at the University of Bradford. For the early part of his career he was a science teacher in secondary and further education, both abroad and within the UK. His career in pharmacy has included various positions as a community pharmacist-manager which has involved medicines advisory work for care homes. In 1993 he completed a pharmaceutical industry research project as part of an MSc degree in pharmacology. For several years he was national Pharmacy Training Manager for Lloyds Pharmacy. In 2005 he joined the Leicester School of Pharmacy at De Montfort University where he works as a Principal Lecturer in Pharmacy Practice. He is author of the *Community Pharmacy Handbook*, published in 2008, and has several publications on subjects related to pharmacy practice. Currently he is working on his doctoral research in the area of pharmacy education.

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Peter Rivers studied pharmacy at Sunderland Polytechnic before registering as a pharmacist in 1976. He began his career working as a pharmacist in hospitals and the community, then completed an MSc in pharmacotherapeutics at the Leicester School of Pharmacy. Peter's interest in the needs of carers arose through his work with Derbyshire care homes in the 1980s, where he introduced and evaluated the Monitored Dosage System to improve the safety and efficiency of administration of medicines. This work led to the completion of his PhD at the University of Wales in 1988 and a career move into higher education. As a teacher and practitioner of research at the University of Derby, he led postgraduate courses for pharmacists and other health and social care professionals. In 2009 he joined the Leicester School of Pharmacy at De Montfort University to take a lead in pharmacy practice research.

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PART I

Introduction to medicines

CHAPTER 1

Introduction to medicines

Scenario
Davinder is 73 and has been prescribed an antibiotic. He explains to you that he has lost the patient information leaflet (PIL) that he was given with his medicine. Davinder asks if you could access some information from the internet, as he is very concerned about the side-effects described in the leaflet.

Checkpoint

Before reading on, think about the following questions to identify your own knowledge gaps in this area.

1. How do you find out accurate and reliable information about medicines?
2. Describe how medicines are legally classified.
3. What is the difference between an NHS and private prescription?
4. Name some medicines that must be stored in a Controlled Drugs cabinet in a care home.

What is a medicine?

When people refer to a 'drug' they usually mean a chemical that will alter the way that the body functions and have a specific effect. The term is often used to describe illicit substances. The term 'medicine' has a more specific meaning and a dictionary definition is: 'any drug or remedy for use in treating, preventing or alleviating the symptoms of disease' (*Collins English Dictionary*, 2011). The terms 'drug' and 'medicine' are often used interchangeably, but ideally the term 'medicine' should be used when referring to an agent that has some benefit. The community pharmacist is increasingly seen as the medicines expert within the healthcare team, and has an important role in ensuring that people obtain maximum benefit from their medicines.

Role of the pharmacist as a medicines expert

The education and training of a pharmacist involves completion of a four-year Master of Pharmacy degree course, followed by one year of pre-registration training in practice. Both of these stages are regulated by the General Pharmaceutical Council, which is the professional regulatory body for pharmacy. The pre-registration training involves successful completion of both competency-based assessment and a final Registration Examination before the newly qualified pharmacist is permitted to work in either hospital or community pharmacy. The pharmacy degree course covers a wide range of subjects and has a particular emphasis on the relationship between pharmaceutical science and the practice of pharmacy. The main subjects include:

- pharmaceutical chemistry (scientific principles important in the understanding of pharmaceutical products)
- pharmacology (the study of how medicines act on the body)
- pharmaceutics (the study of how the raw drug material can be formulated into a suitable dosage form for the patient)
- pharmacy practice (the study of subjects such as law, ethics, supply of medication, communication with prescribers and patients).

On qualification the pharmacist has a wide range of career options, but most pharmacists work in a community pharmacy where there are opportunities to provide pharmaceutical care to the local population. Some pharmacists choose to undertake additional study and become independent prescribers. The pharmacist has specialist knowledge of medicines and this can be used in a wide range of situations. Some examples of the contribution of the community pharmacist are summarised in Figure 1.1. The community pharmacist works within a contractual framework that is designed to provide a range of quality health services. Some of these services are deemed to be essential, and include such areas as dispensing, public health advice, signposting to other health and social care agencies, supporting self-care and the safe disposal of medicines. Other advanced services require that the pharmacist has undertaken further training and the pharmacy is accredited to provide an individual Medicines Use Review (MUR) service or support people who are taking new medicines. Some pharmacists are able to provide higher level enhanced services, such as running a smoking cessation clinic, offering a cardiovascular risk assessment service or an advice service to residential and nursing care homes.

Clearly your local pharmacist has a lot to offer in terms of support and advice about the use of medicines in a care setting. This covers a range of situations, from

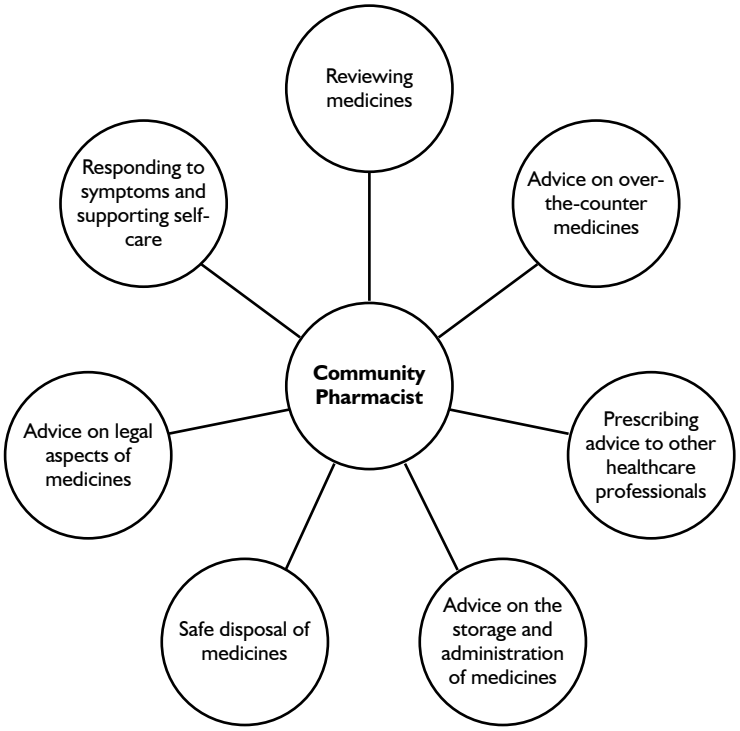

Figure 1.1 Some examples of the contribution of the community pharmacist as the 'medicines expert'.

the person who is self-medicating but needs support from a relative or neighbour, to the more formal arrangement with a domiciliary care worker or a care worker in a residential or nursing home. Increasingly pharmacists are concerned with people taking medicines correctly, and this often involves trying to solve common problems or offer advice, support and appropriate information.

Finding information on medicines

In the UK, current prescribing guidelines state that, in general, medicines should be prescribed using their generic (or approved) name rather than the proprietary or brand name. The generic name is also sometimes known as the recommended international non-proprietary name (rINN). For example ibuprofen is the generic name of a common painkiller, but this is also available as the branded product Brufen®. Generic or approved names tend to be longer and related to the active

ingredient in the medicine. It is sometimes possible to work out the type (or family) of medicine from the ending of the approved name. For example 'beta-blockers' end in 'ol' and have names such as atenolol and metoprolol. By contrast, a proprietary name is sometimes related to the action of the medicine and is easier to pronounce. For example a proprietary name of atenolol is Tenormin® and a proprietary name of metoprolol is Lopresor®. Both of these branded names reflect the use of these medicines in lowering blood pressure. For ease of communication it is helpful always to refer to the proper generic name when discussing medicines. There are some exceptions to this principle when it is important that the patient receives exactly the same dosage form. For example, if a person with epilepsy is stabilised on a certain epilepsy medication it is critical that they receive exactly the same dosage form each time, so the prescriber will then use the proprietary name.

There is a lot of information available on medicines and it is important to establish the most useful and reliable sources. Commonly used reference sources when trying to find out information on medicines are:

- *British National Formulary* (BNF) – reference text
- electronic Medicines Compendium – online information
- NHS Direct – telephone helpline.

British National Formulary

The *British National Formulary* is the definitive reference source that is used by healthcare professionals. It is a joint publication of the British Medical Association and the Royal Pharmaceutical Society that is published every six months. The material contained in this publication is agreed by a committee made up of different representatives of different healthcare professionals. The book is mainly about medicines that are prescribed in the UK and provides very little information on medicines that are promoted for purchase by the public. Information in the BNF is mainly drawn from manufacturers' product literature, UK health departments, regulatory bodies and the latest clinical guidelines. The BNF content is updated by subject and clinical experts and is also available in an online version. A version of the BNF for children is also available.

Finding information online

One of the problems encountered when trying to find out information about medicines is the vast amount of information on the internet. Some of this information is reliable and relevant to medicines in the UK; other information may be unreliable and not always relevant. It is important to note that any 'information' can be posted on the internet and the quality and accuracy of information cannot

always be assured. If the website is not based in the UK, then different laws will apply to the sale and supply of medicines. When searching for information about medicines it is quite common to use a major search engine, such as Google or Yahoo!, which will give you several results very quickly. However, many of the sites may be unsuitable, so you are advised to use one of the websites referred to in this book, which contain safe and regulated information.

When evaluating websites it is useful to ask the questions: who, when and why?

- Who exactly has produced the information? In the UK the most reliable sources are linked to the NHS, academic and professional organisations.
- When was the information produced? If the website has not been updated in the past few years it is likely that the information presented will be out of date. National guidelines on the use of medicines are constantly changing and it is important to use information that is current.
- Why has the information been provided? For example, is the information linked to the sale of a particular product where there may be a bias in how the information is presented?

The electronic Medicines Compendium (eMC; http://www.medicines.org.uk/emc/) provides a range of useful and accurate information provided by medicines manufacturers. There are two main types of information provided:

- **Summary of product characteristics** (SPCs), which provides a summary of the detailed technical information associated with a medicinal product. Some of this information can be readily understood by members of the public, but other parts of the SPC are more technical and designed for healthcare professionals.
- **Patient information leaflets** (PILs) are designed to be a more 'user friendly' version of this information and must be supplied with a medicine. These leaflets can often cause concern, as they often contain a long list of possible side-effects. The manufacturer is required to state possible side-effects that have been documented during the development of the medicine. It is important to note the relative importance and how likely these side-effects are when looking at this type of leaflet. This information is also available for the visually impaired at XPIL (http://xpil.medicines.org.uk/). Typically information in a PIL states:
  - the name of the medicine and the manufacturer
  - why the medicine is usually prescribed
  - typical doses and how it is administered

- if the medicine interacts with other medicines
- a list of circumstances when the medicine should not be taken (contraindications)
- possible side-effects
- how the active ingredients work
- how the medicine should be stored.

NHS Direct

NHS Direct is a 24 hour telephone advice line that is staffed by nurses and is a means of obtaining information and advice on healthcare. Callers are signposted to appropriate services and have faster and easier access to information about NHS services. Advice about medicines can be obtained by telephone from NHS Direct on 0845 4647. After taking your name and telephone number a healthcare professional will contact you by telephone to answer your queries. A similar service is available in Scotland where you can call NHS24 on 08454 242424.

Medicines and the law

The Medicines Act (1968) uses three categories to classify medicines:

- general sales list (GSL)
- pharmacy medicine (P)
- prescription only medicine (POM).

An explanation of these different categories is provided in Table 1.1.

The first two legal categories (GSL and P medicines) are collectively known as over-the-counter (OTC) medicines or non-prescription medicines. To find out what legal category a particular medicine is in you can refer to the eMC website for the SPC as described above. Medicines in the P or POM category are also clearly marked on the product with the letters inside a box: POM P.

Prescribers

Until fairly recently, only doctors and dentists were allowed to prescribe medicines in the POM category. This situation has changed following the publication of the *Crown Report* in 1998, which recommended changes to the prescribing system (Department of Health [DoH], 1999). Nurse prescribing was introduced in an effort to improve access to medicines, and there is now the use of the terms 'independent prescribing' or 'supplementary prescribing'. An independent prescriber can assess patients, make a diagnosis and prescribe a suitable medication. A supplementary prescriber prescribes according to

Table 1.1 Legal categories of medicine.

Legal category	Explanation
GSL	General sales list medicines, as the name suggests, are available to the public through a variety of retail outlets, for example supermarkets and the local garage. This list includes a wide range of medicines used for common symptoms and have been placed in this legal category as they are considered safe enough to be sold by a person without any medical or pharmacy background. The law is very specific about the pack sizes and formulations of these medicines.
P	A pharmacy medicine is a medicinal product that can be sold from registered pharmacy premises by a pharmacist, or a person acting under the supervision of a pharmacist. The classification of a medicine as a P medicine is due to a number of issues: ■ the medicine may have the potential for misuse (for example codeine-based products) and need supervision during the sale ■ the medicine may require the expertise of the pharmacist to supervise the sale (for example some products for colds contain decongestants that could raise blood pressure and would therefore be unsuitable for certain people) ■ the medicine may have been deregulated and moved from the prescription only medicine (POM) category to the P category and need careful supervision.
POM	Prescription only medicines are only available on a prescription written by an appropriate practitioner. There are different types of prescriber and prescription forms, which are explained later in this chapter.

a clinical management plan for an individual patient that has already been assessed and diagnosed by a medical practitioner.

Today there are a number of authorised prescribers, such as general practitioners (GPs), dentists, pharmacists, health visitors, physiotherapists, podiatrists and optometrists. There are varying levels of restriction on different types of prescriber. For example, GPs and dentists can prescribe any medication. However, if the prescription is an NHS prescription the dentist is restricted by the list in the *Dental Practitioner Formulary* and the GP cannot prescribe certain items on a list of items that are deemed to be too costly or not seen to be effective. This list is updated monthly and is available in a document called the Drug Tariff. Prescribers are also asked to adhere to local formulary guidelines that set out prescribing policies in the local area. Other prescribers are defined as non-medical prescribers and it is important that they only work within their own area

Table 1.2 Examples of non-medical prescribing.

Healthcare professional	Prescribing restrictions
Nurses	Nurse independent prescribers may prescribe any medication with the exception of a limited list of Controlled Drugs listed in the BNF.
	Community nurses who have completed a training programme are permitted to prescribe items that appear in the *Nurse Prescribers' Formulary* in the BNF.
Optometrists	Optometrist independent prescribers may prescribe any medicine for eye conditions affecting the eye and the tissues surrounding the eye. Optometrists are not permitted to prescribe Controlled Drugs or injections.
Pharmacists	Pharmacist independent prescribers may prescribe any medicine for any medical condition.

of competence and expertise. It is important to note whether the prescriber has independent or supplementary prescriber status, as different prescribing rights will apply. Some examples of non-medical prescribing are provided in Table 1.2.

Prescriptions

Currently prescriptions are paper documents which are usually computer-generated. Occasionally prescriptions are handwritten, though this can lead to problems of interpretation. There are essentially two types of prescription:

- National Health Service (NHS) prescriptions, which are subsidised. The most common type of form is the green FP10 form issued by a GP. Examples of other NHS forms are provided in Table 1.3.
- Private prescriptions, where the patient pays the full amount for the cost of the medicine.

Different types of prescription form are used in Wales, Scotland and Northern Ireland. Private prescriptions vary in their appearance, as they are often on headed notepaper with the details of the prescriber. The exception to this is when a controlled drug is prescribed privately: it must be on a pink (FP10PCDSS) form.

There is a steady move to replace NHS paper forms with electronic prescriptions, which will have the same legal status as a paper prescription. The advantages of an electronic format are that it:

Table 1.3 Some examples of common types of NHS prescription forms in England.

Form reference	Colour of form	Explanation of how form is used
FP10NC	Green	A pre-printed form for use by GPs and hospital based prescribers
FP10P	Lilac	A form for handwritten prescriptions by a nurse or supplementary prescriber
FP10D	Yellow	Blank form for computer-generated or handwritten prescriptions from a dentist
FP10MDA	Blue	A drug misuse instalment prescription for use by a GP or hospital-based prescriber

- is more convenient for the patient
- will ease the ordering of repeat medication
- will make information more readily available to all members of the healthcare team and provide continuity of care.

The prescription form may have a single item or a number of items on the same form. The current system is that each item on an NHS form is charged a standard amount. This charge is irrespective of the cost of the medicine (which may be considerably more or less than the standard charge). Under the current regulations most prescriptions that are dispensed are exempt from prescription charges, due to the age of the patient, specific medical conditions or other situations listed on the back of an NHS prescription form.

A prescription for a POM must comply with certain legal and other requirements for the prescription to be dispensed. If certain details are missing this may mean a delay in the person obtaining their medicine, so it is useful in a care setting to have some awareness of these issues. For example, if the signature of the prescriber is missing and this is noticed quickly, the signature can be obtained and any delay with the medication avoided. Table 1.4 provides a summary of the main legal requirements of a prescription for a POM. All prescriptions should be in indelible ink.

Controlled Drugs

Some prescription only medicines require a greater level of control and regulation relating to their possession and supply. These are called Controlled Drugs (commonly referred to as CDs), which are subject to the Misuse of Drugs Act 1971. A common classification of CD medicines is the division into Classes A, B

Table 1.4 Summary of information needed on an NHS prescription form.

Information	Reason
Signature of prescriber	Prescriptions must be signed by the prescriber in his or her own name, so that the prescription can be attributed to a particular prescriber.
Address of the prescriber	The address of the appropriate practitioner is required. Other contact details, such as name and telephone number, are useful if the prescriber needs to be contacted if there are any problems with the prescription.
Date	The date of the prescription should be clearly marked. There is legislation that requires certain medication to be dispensed within a certain time limit. For example, a POM must be dispensed within six months of the date on the prescription.
Particulars	These details are needed so that the type of practitioner is clear. They may be prescriber qualifications or details of professional registration.
Name of the patient	This is important (with the address) in providing unique patient identification and ensuring that the medicine is received by the correct patient.
Address of the patient	Important identifying information (but not required for prescriptions written by EEA or Swiss prescribers).
Age of patient	This is legally required if the patient is under 12 years of age (but not required for prescriptions written by EEA or Swiss prescribers). Normally this is expressed as either date of birth or age in years and months. With a computer-generated prescription this information is usually added automatically.
Name of the medicine, strength and dosage form	These details are necessary in order to dispense the prescription correctly.
Dose	This information allows the pharmacist to check that the correct dose has been prescribed. In some cases there are no dose instructions and the prescription is written 'Take as directed'. It is important in these cases to ensure that the patient is clear how to take the medicine. In a care setting this is particularly important where the medicine is being administered by a third party, and any ambiguity needs to be discussed with the pharmacist.

Table 1.4 (*continued*)

Information	Reason
Dose (*continued*)	Latin abbreviations are still used on prescriptions and a list of common abbreviations can be found in the back of the BNF. Common examples include: ■ i bd: take one twice a day ■ i tds: take one three times a day ■ ii qds: take two four times a day The dosage instructions may also contain additional instructions, such as taken before food for certain antibiotics.
Total amount	For ongoing treatment this is usually 28 days' supply. The amount is written either as a total quantity or the length of a treatment course. For example, the prescriber may prescribe amoxicillin 250 mg capsules and state the total quantity (21) OR state seven days and the dose of one three times a day, so that the total quantity of 21 can be calculated.

and C that reflects the potential amount of harm that these may do to an individual if used inappropriately. Class A drugs are considered the highest level in terms of possible harm and any offences related to possession or supply of this class attract higher penalties. Drugs can be moved between classes: for example in recent years cannabis was moved from Class B to Class C and then back to Class B. The classification that is used when the CDs are used as medicines is based on different schedules and is outlined in Table 1.5.

Storage

Care homes, alongside all other types of institutions such as hospitals and outpatient clinics, are required to comply with the requirements of the Misuse of Drugs (Safe Custody) Regulations. The regulations state that all CD medicines kept on the premises must be stored in a clearly defined CD cupboard. The CD cupboard must be either a separate lockable metal cupboard or a lockable metal cupboard within a cupboard that is fixed and not portable. The cupboard should have a special double-locking mechanism that complies with the legislation and it is important that the key cannot be removed while the door is open. The cupboard should always be fitted to a solid wall or to a wall that has a steel plate mounted behind it. The keys to the CD cupboard should be with the keys to the other medicine cabinets and carried by an authorised member of staff at all times. Under no circumstances should other valuable items such as money or jewellery

Table 1.5 Classification of Controlled Drugs.

Schedule	Examples
1	These are not used for a medicinal purpose and a licence is needed for their production, possession or supply. Examples include hallucinogenic drugs such as 'LSD' or ecstasy-type substances. They may be obtained under licence, for example in scientific research.
2	These have a high level of control in terms of how a prescription needs to be written and how they are stored, supplied and recorded. Examples include opiates (for example, diamorphine and methadone) and major stimulants (for example, amphetamines).
3	These also have a high level of control but are not recorded in a Controlled Drugs Register in a pharmacy. Examples include minor stimulants and other drugs such as buprenorphine, temazepam, midazolam and phenobarbital. These are less likely to be misused and less harmful than Schedule 2 drugs.
4	This Schedule is split into two parts: Part I contains benzodiazepines, such as diazepam, and Part II contains anabolic/androgenic ('body building') steroids and growth hormones.
5	This Schedule contains preparations that contain small amounts of medicines such as codeine, pholcodine and morphine. The nature of the preparations is considered to be of negligible risk due to their low strength.

be stored in the CD cupboard. If a client is self-medicating then any CDs that they have must be stored in a locked drawer or cupboard in their room.

In a care home setting the regulations apply even though the medicine is prescribed and is strictly speaking the property of the client. A special Home Office licence is needed if the home wishes to order stocks of CDs. Other exemptions where stocks of CDs may be ordered are where the home is owned by a charitable organisation or maintained by public funds, such as a hospice.

CD Register

The CD Register must be a bound book with numbered pages and there should be a separate page for each form and strength of each medicine for each service user. Any CD medicines received by the home must be entered in the book immediately, and when a dose is administered this should be recorded and witnessed by another member of staff. A running total should be maintained so that the balance of CDs in the cupboard can be checked regularly. There should be no crossings out or alteration in a CD register and any amendments should be made by a clear footnote.